4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dear Healthcare Provider Letters: Improving Communication of Important Safety Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0754. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Improving Communication of Important Safety Information--21 CFR Part 200

OMB Control Number 0910-0754--Extension

This information collection supports Agency regulations and recommendations found in associated Agency guidance, as discussed below. Under section 705 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 375), the Secretary of the Department of Health and Human Services (the Secretary) may require dissemination of information for drugs in situations that involve, in the Secretary's opinion, "imminent danger to health, or gross deception of the consumer." Implementing regulations are found in § 200.5 (21 CFR 200.5) and outline the general provisions for "Dear Healthcare Provider" (DHCP) letters that manufacturers and distributors disseminate about important drug warnings, important prescribing information, and important correction of drug information. The regulations also prescribe certain format and content instructions regarding the dissemination of covered information. Manufacturers or distributors send DHCP letters to physicians and other healthcare providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. We developed the guidance document entitled "Dear Healthcare Provider Letters: Improving Communication of Important Safety Information" (January 2014), available at https://www.fda.gov/media/79793/download, to provide instructions and recommendations to respondents on implementing the applicable requirements. All Agency guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115.

In addition to the content and format recommendations for each type of DHCP letter, the guidance also includes recommendations on consulting with FDA on: (1) how to develop a DHCP letter; (2) when to send a letter; (3) what type of letter to send; and (4) how to assess the letter's impact.

In the *Federal Register* of June 24, 2022 (87 FR 37871), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were

received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity; 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Time per Response (in Hours)	Total Hours
Preparation of DHCP letters; § 200.5	6	1.3	8	100	800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have identified 24 DHCP letters that 18 distinct sponsors submitted to FDA during the 3-year period (2019 to 2021). Based on our Document Archiving, Reporting, and Regulatory Tracking System, we estimate eight DHCP letters will be submitted annually from six application holders. Based on our experience, we assume that each letter will require 100 hours to prepare and disseminate as recommended in the guidance. Our estimate reflects a downward adjustment by five responses and 500 hours annually. We attribute this decrease to the effectiveness of the guidance and the decreased number of DHCP letters submitted for FDA review.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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